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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/397,494 09/15/99 BALABAN

D 18547-037510

020350 TM02/1109
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

AMSBURY, W
ART UNIT PAPER NUMBER

2171
DATE MAILED:

11/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/397,494

Applicant(s)

BALABAN ET AL.

Examiner

Wayne Amsbury

Art Unit

2171

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6. 6) ☐ Other:

CLAIMS 1-25 ARE PENDING

1. The Appendix of software specifications is of record in the file, but if it is to be printed at issue, it must be inserted by amendment prior to the claims; if not, (which is recommended), all references to it should be deleted by amendment from the Specification.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,308,170 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because: The instant claims are a broad description of the database mechanisms, with variations and housekeeping elements that would be obvious to one of ordinary skill in the art at the time of the invention, that are required to implement the specific claims of '170.

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For example, claim 15 of the instant application utilizes multiple databases, whereas claim 23 of '170 utilizes a single database. However, the Specification of '170 addresses the use of multiple databases, and with the growth of files of '170, the sources of the files, and the provision of public databases, it becomes obvious, desirable, and efficient to allow for multiple databases as sources of data.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lincoln et al (Lincoln) USPAT 6,303,297 in view of Kris et al (Kris) USPAT 6,238,869 B1.

Lincoln teaches the use of databases to store and analyze expression sequence data and to correlate a primary database with other public databases. However, Lincoln does not explicitly present results in graphical form or address some of the aspects of a probe array determination of sample results and status, both taught in Kris. Kris does not explicitly address the use of multiple databases. It is clear that the amount of data generated in Kris requires organized storage and correlation, as would be provided by Lincoln, and that the use of public databases for enhancing and extending available data is more efficient than generating the same data from scratch.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the systems of Lincoln and Kris in order to store, organize, analyze, correlate, and present the volume of data required for high throughput probe array sampling of gene sequences.

As to claim 15, it is a broad description of the queries applied to distributed databases, where the specific data is derived from experiment, viewed, and presented. The specific database used to access multiple databases clearly determines a user specification of interest to form a filtered result.

As to claim 1, the library construction of Lincoln is one form of producing a sample history. Kris demonstrates the normal use of expression sequences, as at COL 43-44 and elsewhere.

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Access to public databases and remote databases, such as GenBank discussed in Lincoln is generally via the Web. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide Web access to the results because it provides efficient access from remote locations.

The limitations of claims 10, 16 and 25 are rejected in the analysis above, and these claims are rejected on that basis.

As to claim 4, Kris is directed to the application of a probe array.

As to claims 2,3,5,6,7-9, these are housekeeping details taught within both Lincoln and Kris. One such teaching is the status of a drug candidate in Kris at COL 2 lines 26-31. Deriving a result is the point of an experiment. Lot numbers are clearly necessary in order to organize a large number of experiments or assays that vary from sample to sample. Sample type is an inherent parameter of applying different test samples to each of 96 wells in a plate in Kris COL 2 lines 47-51. Clearly a set of sample experiments subsumes some project. The use of multiple samples for an experiment and vice versa is simply standard laboratory technique.

The elements of claims 11-14 and 17-24 are rejected in the analysis above and these claims are rejected on that basis.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Wayne Amsbury whose telephone number is 703-305-3828. The examiner can normally be reached on M-TH 7-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Black can be reached on 703-305-9707. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7239 for regular communications and 703-746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9700.

WPA
November 6, 2001


WAYNE AMSBURY
PRIMARY PATENT EXAMINER